MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
AUGUST 22 & 23, 2011

IDAHO STATE CAPITAL BOISE, IDAHO

This meeting of the Board was held to conduct regular Board business.

Chairman Richard de Blaquiere, Pharm D, called the meeting to order on August 22, 2011 at 12:05 p.m. In attendance were Board members Berk Fraser, R.Ph.; Nicole Chopski, Pharm D; Holly Henggeler, Pharm D; and Mark Johnston, R.Ph., Executive Director; Jenifer Marcus, DAG; Andy Snook, DAG; Jan Atkinson, Senior Compliance Officer; Lisa Culley, Compliance Officer; Mike Brown, Compliance Officer; Gina Knittel, Compliance Officer; and Wendy Hatten.

The minutes of the June 16, 2011 Board meeting and the teleconference Board meetings of July 7, 2011, and August 1, 2011 were reviewed. Mr. Fraser motioned to approve all three (3) minutes as written. Dr. Henggeler seconded. The motion carried unanimously.

Mr. Johnston introduced Mr. Ned Milenkovich, Pharm D, JD, of McDonald Hopkins Attorneys at Law and Mr. David Stanford of Rexam who presented proposed regulations in connection with product container integrity which would protect patient safety by ensuring that containers reach the marketplace only after they have met certain minimal quality assurances. After much discussion that included all Board members, Mr. Johnston, Jennifer Marcus, and Lynette Berggren, contracted legal consultant, Dr. Henggeler motioned to table changes to regulation until further research is done regarding possible product container issues, specifically in Idaho pharmacies. Mr. Fraser seconded the motion. The motion carried unanimously.

Mr. Al Carter R.Ph., Manager of Pharmacy Affairs for Walgreens presented proposed regulation changes to allow for central fulfillment. After much discussion the Board determined the following:

- Mr. Carter's proposed central fulfillment can be performed from out-of-state mail order pharmacies without additional changes to rule.
- A pharmacy located within Idaho can perform the cognitive services functions of Mr. Carter's proposed central fulfillment with other Idaho pharmacies, with proper documentation of activities and without additional changes to rule.
- A pharmacy that is located outside of Idaho may not only perform cognitive services into Idaho as proposed by Mr. Carter without rule or statute change, however, an Idaho licensed pharmacist may, pursuant to rule 165.
- The Board's legislative work list should include statutory changes that would allow for the registration of non-resident pharmacies, in addition to mail service pharmacies, such as central fill pharmacies to address issues such as

prescription drug order transferring and counseling on depoted prescriptions from central fill pharmacies.

Mr. Milenkovich, on the behalf of Flavor RX, and Mr. Carter presented proposed regulations regarding prescription flavoring. After much discussion the Board agreed to add new proposed rule 135 to the draft, entitled “drug product flavoring”, which reads: “a flavoring agent may be added to a drug product upon request by the prescriber, the patient, or the patient’s agent.” Additionally, a definition of “flavoring agent” was added.

Dr. de Blaquiere called the meeting to order after a short break.

On behalf of Mike Merrill, R.Ph, of Mikes Pharmacy and Jason Bailey, Pharm D, of Teton Pharmacy, Mr. Johnston presented the request for clarification of rule 177. A demarcation line between limited service pharmacies and retail pharmacies was requested. Reece Christensen and Lisa Cowley of Heartland Pharmacy also presented public comment. After a lengthy discussion and review, the Board tabled the discussion until Mr. Johnston could research the impact of the Board’s limited service pharmacy registration category on manufacturer’s preferred pricing and until Mr. Johnston could obtain input from other Idaho registered limited service pharmacies. The proposed rules do give more structure to the category of limited service pharmacy. Concerned parties should review the proposed rules concerning limited service pharmacies carefully and, if necessary, provide public comment.

Mr. Johnston presented a reciprocity application for Mr. Jay Bawden, R.Ph. Mr. Bawden’s application contained information that, per prior Board direction, would need to be reviewed by the Board prior to consideration of licensing. Mr. Bawden was present and clarified for the Board information provided on his application. Dr. Henggeler motioned to accept the reciprocity application for consideration of licensing. Dr. Chopski seconded with the comment that all required application materials be provided to the Board office. The motion carried unanimously.

Dr. de Blaquiere called for public comment. No one commented.

Dr. de Blaquiere asked Mr. Johnston to lead the agenda topic entitled legislation review. Mr. Johnston reported that the legislative idea form and draft language that updates the schedules of controlled substances remains unchanged from the last meeting. Additionally, Idaho State Police and FBI have informed the Board that they will continue to process fingerprint requests for student pharmacists and technician applicants, so the legislative idea form that specifically added these two categories to statute will not be acted upon. Mr. Johnston explained that the Governor’s office would most likely not be approving the Board’s expedited partner therapy legislative idea forms or a similar one from Health and Welfare, as they expect the Idaho Medical Association to take the lead. Finally, Mr. Johnston explained proposed changes to statute 37-2726 that would:

- clarify that interstate PMP data sharing is allowable
- allow pharmacist access to PMP data for the provision of pharmaceutical care

- add a misdemeanor penalty for authorized users for the misuse of data that was obtained via not securing their user identification and passwords
- allow the Board to block access to PMP data for cause
- increase certain penalties to felonies.

The Board approved of said legislative action via unanimous consent.
Dr. Chopski motioned to adjourn. Mr. Fraser seconded. Meeting adjourned at 5:18pm.

August 23, 2011

Chairman Richard de Blaquiere, Pharm D, called the meeting to order on August 23, 2011 at 8:05 a.m. In attendance were Board members Berk Fraser, R.Ph.; Nicole Chopski, Pharm D; Holly Henggeler, Pharm D; and Mark Johnston, R.Ph., Executive Director; Jenifer Marcus, DAG; Andy Snook, DAG; Fred Collings, Chief Investigator; Jan Atkinson, Senior Compliance Officer; Lisa Culley, Compliance Officer; Mike Brown, Compliance Officer; Gina Knittel, Compliance Officer; and Wendy Hatten.

Mr. Roger Hales, Esq. and Jack Zarybnisky, OD, Board of Optometry Chairman presented a proposed rule change for the Board of Optometry. The Board of Optometry desires to strike from rule a drug formulary that lists certain individual drugs that an optometrist may prescribe and list certain categories of prescriptive authority instead. Dr. Henggeler motioned to support the proposed rule changes. Mr. Fraser seconded. The motion carried unanimously.

Mr. Johnston presented the travel calendar. Teresa Anderson, PMP program manager and Steve Draper contracted information technology specialist attended the PMIX Architecture conference in Washington, DC in August. Mr. Johnston will be attending the NACDS Conference on technology in Boston in a couple of days. Mr. Johnston will attend the NABP Interactive Executive Officer forum in Chicago, IL in September. Mr. Johnston will be teaching a continuing education class at the ISHP Fall Meeting in Sun Valley, ID in September. Mr. Johnston will attend the Deans Advisory Council in Pocatello in October. Mr. Johnston and Mr. Fraser will be attending the NABP District Meeting in Seattle, WA in October. The inspectors will be attending the Clear Conference in Pittsburgh, PA in September. Ms. Anderson will be attending the NASCA Conference in Portland, ME in October. The next Board meeting will be at the Hilton Garden Inn/Spectrum in Boise, ID on October 26 & 27, 2011. Mr. Johnston and Ms. Marcus will be attending the ASPL Fall Meeting, St Petersburg, FL in November. At least one (1) inspector will be attending the NABP Interactive Compliance Officer Forum, in Chicago, IL in December. Dr. Henggeler inquired regarding the amount of meetings that will be planned for next year. Based on the average number of past Board meetings and the increase of disciplinary actions Mr. Johnston suggested that the Board would benefit with a one (1) day meeting every sixty (60) days. The specific dates will be set at next board meeting.

Mr. Snook represented the Board in the matter of Mr. Dennis Beach's R.Ph. reinstatement hearing. Mr. Fraser recused himself. Mr. Beach represented himself. After opening statements by Mr. Beach and Mr. Snook, Dr. Henggeler motioned that the

Board follow Southworth Associates', the administrator of the Board's pharmacy recovery network (PRN), recommendation of a three (3) to five (5) day inpatient evaluation, and in addition that Mr. Beach be placed on two (2) more years' of probation. The motion died for lack of a second. Dr. Chopski motioned to follow PRN's recommendation: if no issues are found that the Board enter into a stipulation and order with Mr. Beach, allowing reinstatement with standard probation, continued drug testing, and a provision that Mr. Beach not be a pharmacist in charge. Dr. Henggeler seconded for discussion. Dr. de Blaquiere suggested the Board accept PRN's recommendation and then discuss inpatient evaluation results at the next available Board meeting. Teleconferencing would be acceptable, so that Mr. Beach would not have to travel from Colorado again. Dr. Chopski withdrew her initial motion and made a new motion that the Board follow PRN's recommendation and that the results be brought before the Board at the next available Board meeting following the inpatient evaluation results. Dr. de Blaquiere seconded the motion. The motion carried unanimously.

Mr. Snook presented case number BOP 11-031 stipulation and consent order in the matter of Charlene Dehaven, MD involving violations of Idaho Code 37-2732(c), 37-2718(a)(4), and violation of rule 454, for ordering significant amounts of controlled substance medications that were shipped to her home address for personal use. For a minimum of two (2) years, Ms. Dehaven shall not be allowed to perform any of the following; Order controlled substances by phone; All orders or prescriptions for controlled substances must be in written, hard copy form, or ordered through electronic prescribing; Ms. Dehaven shall not order controlled substances for office use, and shall not maintain any samples of controlled substances in her office, home, automobile, or any other similar area; or order controlled substances to be dispensed or administered to patients. Also, Ms. Dehaven shall not order controlled substances for personal use and shall abstain from personal use or possession of prescription drugs except as prescribed, administered or dispensed to her by another so authorized who has full knowledge of her history of chemical dependency. Dr. Chopski motioned to accept the stipulation as written. Dr. Henggeler seconded. The motion passed unanimously.

Mr. Snook presented case number BOP 11-061 stipulation and consent order in the matter of Lee Self, MD involving violations of Idaho Code 37-2720, 37-2718(a)(4), and rule 496, for being unable to provide documentation evidencing that controlled substances ordered by Ms. Self were actually dispensed to patients. Ms. Self may petition the Board for modification of the stipulation and consent order or for reinstatement of her controlled substance registration following one (1) year of continuous compliance with the terms of the stipulation and order. For a minimum of two (2) years Ms. Self shall not be allowed to perform any of the following; order controlled substances by phone; All orders or prescriptions for controlled substances must be in written, hard copy form, or ordered through electronic prescribing; Ms. Self shall not maintain any samples of controlled substances in her office, home, automobile, or any other similar area; and shall not order controlled substances to her registered address to be dispensed or administered to patients. Dr. Chopski inquired to Mr. Fred Collings, Chief Investigator as to how compliance will be monitored. Mr. Collings responded that he has notified the wholesalers that Ms. Self surrendered her controlled substance

registration and thus is not eligible to order controlled substances. Mr. Snook added that the Board's stipulation and order will be forwarded to the Board of Medicine, and in addition should Ms. Self choose to petition the Board for reinstatement it is her responsibility to provide the Board with evidence of compliance with the stipulation and order. Dr. Henggeler motioned to accept the stipulation and order as written. Mr. Fraser seconded. The motion passed unanimously.

Dr. De Blaquiere called the meeting to order after a short break.

Dr. de Blaquiere asked Mr. Johnston to lead the agenda item entitled Rules review. After much discussion concerning the proposed rules draft, the Board approved of the language created pursuant to their direction from the 8/1/11 open, public meeting and the following proposed, draft, rule changes:

004: incorporation by reference change in accordance with the Department of Administration, Division of Rules' direction.

010.09: definition of "charitable clinic or center; authorized personnel" changed to be in harmony with rules.

010.32: the word "institutional" was added in front of "facility" in the definition of "institution engaged in the practice of telepharmacy across state lines".

013.b: the word "be" was stricken.

011.18: the first use of "delivered" was changed to "dispensed".

011.22: "medical supplies" was struck from the definition of "retail non-pharmacy drug outlet".

018.01: language was struck to make this rule apply to all reinstatement applicants.

018.02: A requirement of 30 hours of continuing pharmacy education in the prior two years was added as a requirement of an application for pharmacist reinstatement.

041.02: title change: "one-time" was struck.

060.02: the phrase "immediately considered" struck as extraneous.

109: a new rule entitled "drug order minimum requirements" was created, utilizing statutory language and new definition of drug order was added to rule 010.

Dr. De Blaquiere called the meeting to order after a lunch break.

Mr. Johnston presented public comment from Neil Johnson, Regulatory Affairs for Parata Systems, LLC, requesting proposed USP customized patient medication package standards language be added to the rules. The Board determined that

comingling of drugs within one package was allowed without a rule change, as long as each drug was properly labeled on the dispensed container.

Mr. Barry Feely, R.Ph, of Medicine Man North Pharmacy Inc. requested approval to use a commercially available packaging system by Dispill USA. At debate is an existing Board policy that does not allow the use of packaging that can easily be separated into improperly labeled smaller units of use. After a lengthy Board discussion the decision was made to allow Dispill's packaging to be utilized, regardless of the ease of separating the dispensed package into smaller units that are only partially labeled, if the entire package was properly labeled when dispensed.

Legislation and Rule review continued:

110: the phrase "except as differentiation is permitted for a drug order" was added.

111: several non-substantive changes to reduce verbiage were approved.

112.05: the phrase "and must not be filled" was deleted as extraneous.

114.03: the word "dispensed" was struck as extraneous and confusing.

114 &116: language changed to clarify the difference between a "prescription drug order" and a "prescription".

109-120: rearranged to improve flow.

141 &142: the phrase "or other unique identifier" was added to the requirement to document initials.

142: title change: "sterile product labeling" changed to "parental admixture" labeling.

145: a new rule entitled "prescription drug packaging" was added.

200: the "positive ID" rule was changed to pertain to prescribers too.

203: the word "dispensing" was added to the list.

204: the word "deliver" was changed to "dispense", pursuant to the activity, not the statutory authorization.

204.04: title changed.

261.03: title added.

262: the phrase "for destruction" was added after "quarantine", "hospital" was added before "daily delivery system", and "prescription" was added before "device" to clarify language concerning returns.

290.01: the phrase “each automated dispensing and storage system (ADS) is” was deleted as a conflict with the single registration requirement.

290.03: the word “prescriber” was added to list of “PIC or director”.

310: the word “drug” was added in front of “name” and deleted in front of “class” for clarity.

310: the word “injectable” was changed to “intramuscular”.

350.03: the phrase “or another title that conveys the same meaning” was un-struck to allow student pharmacists from other states to use their university name badges. Pharmacist intern and pharmacist extern were added as acceptable name badge titles.

632: the term “by an R.N.” was deleted, as a conflict.

680: a new rule was created to mimic current rule 292.10

700.05: struck in its entirety.

710: a provision was added to mandate ADS use in remote dispensing sites.

711: a grandfathering clause was added.

Mr. Hoagland presented on the topics of pharmaceutical care and medication therapy management (MTM), explaining that the current draft of the proposed rules lists many parameters of MTM that are actually parameters of pharmaceutical care. After much discussion, the Board decided to retain the introductory language in rule 011.03, but replace the list with the five core elements of MTM: medication therapy review, personal medication record, medication related action plan, intervention or referral, and documentation and follow-up. The list previously listed under the definition of MTM was moved to the definition of pharmaceutical care services (rule 11.09), and e (administering drugs and immunizations) was struck as extraneous overlap with statute 54-1704. Dr. Chopski thanked Mr. Hoagland for his persistence in presenting on this topic.

Mr. Johnston requested the Board’s direction regarding the unused portion of appropriated funds for Lynette Berggren, the Boards contracted paralegal, and Sam Hoagland R.Ph., the Boards contracted legal consultant, realizing that addressing the current limited service pharmacy issues head the list. Mr. Johnston presented topics that the Board had previously tabled and the Board prioritized the list as follows:

- Non-resident pharmacy registration and practice standards, including central fill and revising the out of state mail service pharmacy act
- Complete statutes rewrite - per Senator Joyce Broadsword request
- Compounding

The following topics are to be addressed after the prior three are completed in order.

- PRN statutes and rules
- Other drug outlet rules such as cognitive services and nuclear pharmacies
- Emergency preparedness statutes – allows unregistered practitioners to work in state of emergency, refills to be processed without appropriate authorization for pharmacy transfer, temporary mobile pharmacy, prescriptions to be dispensed without authorization, etc.
- Temporary drug outlet rules - per Dan Fuchs
- Emergency key security rule - per the request of Board Inspectors and Rite Aid

Ms. Berggren will submit the revised Board rules via email to Board members on Monday, August 29, 2011. The Board will have two days to review and respond. Ms. Berggren will then, via email submit the final version to Dennis Stevenson, with a carbon copy to Bernice Myles.

Mr. Sam Hoagland presented open public comment on the following subjects;

- State and federal label transfer warnings - The federal transfer warning is only applicable to controlled substance prescriptions and the state transfer warning label is applicable to all prescriptions. All of the words required by the federal government are being used and the state is in substantial compliance.
- Expedited Partner Therapy legislative idea – Would be a good issue to refer to the Pharmacy Leadership Council, ISPA & ISHP to possibly work on together.
- Violations regarding prescription monitoring statutes – The state of mind or intent should be taken into consideration when applying punishment. A good reference would be the HIPAA law that has threes (3) levels of sanctions for violations. The highest punishments are applied when information is illegally obtained for personal or monetary gain whereas punishment isn't as severe for negligence or mistakes.

Dr. Henggeler asked Mr. Johnston about a letter that the Board office received from PRN regarding two (2) contracted individuals that are about a year delinquent in paying fees owed to Southworth Associates. The delinquency makes them in violation of their Southworth Associates contract, which in turn makes them in violation of their Board stipulation and order. The Board directed Mr. Johnston to send a "motion to enforce" to notify the individuals that they need to pay fees.

Glenn Luke presented the Board's financial report for the Board office:

- Regarding fiscal year 2012, the comparison of budget to expenses as of July 31, 2011, for the first months fiscal summary indicated operations were slightly over budget, but that is not uncommon for the beginning of the fiscal year and will be monitored accordingly for the rest of the year.
- Regarding fiscal year 2011 the comparison of budget to expenses as of June 30, 2011, show all but $1637.00 of appropriated monies was spent, much of which was needed to facilitate the Board's move to a new office.

- Spring Renewals Summary;
    1. 7030 renewal postcards were mailed
    2. 5891 were eligible to renew online (83.80%)
    3. 5417 renewed online (92%)
    4. 60 renewed online late. None were practicing pharmacist (1.02%)
    5. 1139 were paper only renewals (16.20%)
    6. There is a plan to begin testing to convert some of the license types that are currently paper only renewals to online renewals.
- Budget appropriation request for FY13 which will begin July 1, 2012, in order of priority;
    1. $37,800.00 for the open Customer Service Representative 1 position to be filled.
    2. $290.00 in funds to be moved from operating into personnel.
    3. $96,200.00, for legal fees to rewrite Board statutes.
    4. $4800.00, for the National Association of Boards of Pharmacy (NABP) to inspect telepharmacies. NABP will perform the inspections then charge the Board.
    5. $50,200.00, the remaining funds from the federal grant that was previously awarded for the PMP program.
    6. Two (2) replacement items;
        - $150,000.00 to $250,000.00, for new Board licensing system. The Board staff is currently working with several other state licensing agencies to determine if there would be cost savings in purchasing a licensing system that would accommodate multiple licensing agencies verses purchasing one separately.
        - $28,000.00, for replacement of 2004 Monte Carlo with a midsized hybrid sedan.

Mr. Luke also noted that the Southworth Associates contract with the Board is about to expire and that a value based request for proposal (RFP) has been sent out to establish a new PRN contract.

During inspector Q & A Mike Brown requested clarification regarding expired pharmacist licenses. The inspectors are given a list but do not actively go to the pharmacist. The Board is agreeable with the current process.

Mr. Fraser motioned to enter executive session, pursuant to Idaho Code 67-2345(1)(b). Dr. Chopski seconded. Dr. de Blaquiere did a roll call, and the vote was unanimous to enter executive session at 5:15 p.m. Mr. Fraser motioned to end executive session and the meeting at 5:24 pm and Dr. Henggeler seconded. All were in favor.